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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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028381
ARNOLD & PORTER
555 12TH STREET, N.W.
WASHINGTON DC 20004

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EXAMINER

OZGA, B.

ART UNIT

PAPER NUMBER

1651

DATE MAILED:

7
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/523,102

Applicant(s)

SI ET AL.

Examiner

Brett T Ozga

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-66 is/are pending in the application.
- 4a) Of the above claim(s) 43-66 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claims ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42, drawn to methods for treating neovascularization, classified in class 514, subclass 575.
- II. Claims 43-66, drawn to ophthalmic compositions for treating neovascularization, classified in class 514, subclass 912.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, batimastat can be used to promote general health instead of treating neovascularization.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter placing an undue burden to search divergent subjects in the non- patent literature, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

During a telephone conversation with Andrew Brenc on 5/7/01 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-42. Affirmation of this election must be made by applicant in replying to this Office action. Claims 43-66 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Claims 1-4, 7-10, 13-20, 23-28 and 31-42 are rejected under 35 U.S.C. 102(e) as being anticipated by D'Amato et al. (US 6017949).

The instant application claims a method for treating retinal neovascularization in a mammal comprising topically administering to the eye a composition capable of delivering a batimastat compound (0.1- .3% by weight) to the retina, wherein the composition comprises a polymeric suspension agent as well.

Dependent claims further limit by making the mammal a human. They further limit by making the batimastat compound batimastat itself. They further limit by making the polymeric suspension agent a polymer or polycarbophil (0.5-1.5% by weight).

D'Amato et al. teach a method for treating retinal neovascularization in a mammal (human) comprising topically administering to the eye a composition capable of delivering a batimastat compound (batimastat) (0.1- .3% by weight) to the retina (See example 1 and cols. 3, 9 and 10.). They teach the composition comprising a polymeric suspension agent (a polymer) as well. (See col. 11.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 6, 11, 12, 21, 22, 29 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Amato et al. in view of Babcock et al. (US 5538721)

D'Amato et al. teach a method for treating retinal neovascularization in a mammal (human) comprising topically administering to the eye a composition capable of delivering a batimastat compound (batimastat) (0.1- .3% by weight) to the retina (See example 1 and cols. 3, 9 and 10.). They teach the composition comprising a polymeric suspension agent (a polymer) as well. (See col. 11.)

D'Amato et al. do not teach the polymeric suspension agent as a polymer or polycarbophil (0.5-1.5% by weight).


Babcock et al. teach the polymeric suspension agent as polycarbophil (1% by weight) as a topical ophthalmic application. (See example 1, 3 and 4.)

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method of D'Amato et al. by the addition of the polycarbophil of Babcock et al. as the addition of polycarbophil to a topical ophthalmic application is very well known in the art to aid adherence of the product to the eye, as disclosed therein. Thus, in view of the cited references, the artisan of ordinary skill would have been motivated to have practiced the process as recited in the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brett T Ozga whose telephone number is 7033050634. The examiner can normally be reached on M-F 0530-1500, 2nd Wednesday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 7033084743. The fax phone numbers for the organization where this application or proceeding is assigned are 7033084242 for regular communications and 7033053014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 7033080196.


LEON B. LANKFORD, JR.
PRIMARY EXAMINER